AN ATRAUMATIC ENDOTRACHEAL TUBE INTRODUCER AND ATRAUMATIC INTUBATION METHODS

Background of the Invention

1. Technical Field

The present invention pertains to the field of endotracheal intubation.

2. Related Art

Endotracheal intubation is a procedure for creating an artificial airway in a patient by inserting an endotracheal tube ("ETT") into a patient's trachea through the patient's nose or mouth.

Fiberoptic endotracheal intubation is an intubation technique that utilizes a fiberoptic endoscope ("fiberscope") to facilitate the proper placement or exchange of an ETT. A health care provider, using the direct visualization provided by the eyepiece of the fiberscope, directs the fiberscope, with an ETT pre-loaded ("piggy-backed") on the fiberscope's insertion cord, into a patient's trachea. Using the fiberscope as a guide wire, a distal tip of the ETT is then advanced over the fiberscope into the trachea between and beyond the vocal cords.

In an endotracheal tube exchange, an in-place ETT in a patient is withdrawn over a tube exchanger that serves as a guide wire for its removal, and a fresh ETT is thereafter inserted into the patient's airway, by advancement over the tube exchanger, so that its distal tip passes between and beyond the vocal cords.

When an ETT is advanced over the fiberscope or a tube exchanger, the distal tip of the ETT may impinge on the glottis, the epiglottis, the larynx, or other anatomy of the airway,

causing trauma and resisting further advancement into the trachea. The impingement of the ETT on the glottis, the epiglottis or the larynx has been attributed to a cleft that arises between the outer ETT that is concentric with either the inner guiding fiberscope or the inner guiding tube exchanger, over which the ETT rides. As the the ETT is advanced along the fiberscope or tube exchanger, the cleft between them also advances, with a propensity for snaring tissues lying in its path.

The present invention minimizes the risk of trauma to tissues in the course of fiberoptic intubation and ETT exchange by covering the offending cleft with an atraumatic, flexible shroud.

The present invention also protects the vocal cords from trauma as the ETT is passed between them, particularly when vocal cord edema or mild stenosis is present, in both fiberoptic intubation and intubation performed with or without a laryngoscope to facilitate placement or exchange of an ETT.

The present invention additionally offers advantages in both fiberoptic intubation and intubation performed with or without a laryngoscope to facilitate placement or exchange of an ETT, because of a streamlining effect created by the shroud that facilitates smooth insertion of the ETT. This advantage is especially important in difficult intubations when airway visibility is poor or when the opening between vocal cords through which the ETT must pass is very small.

Summary of the Invention

The invention comprises a flexible endotracheal tube introducer ("introducer") for slidably removable disposition within an endotracheal tube ("ETT"), said introducer having a wall defining a lumen extending between a proximal end and a distal end of said introducer, said

wall having an outer diameter that is less than an inner diameter of said ETT, and said wall being circumscribed by an invertible shroud for distal-ward ("forward") flexion and proximal-ward ("rearward") flexion.

Brief Description of the Drawings

FIG. 1 is a schematic illustration of a flexible endotracheal tube introducer oriented for slidably removable disposition within an examplary endotracheal tube.

FIG. 2 is a schematic illustration of a flexible endotracheal tube introducer.

FIG. 3A is a schematic illustration of a shroud of a flexible endotracheal tube introducer in a first substantially frusto-conical shape.

FIG. 3B is a schematic illustration showing a longitudinal (sagittal) cross section of a first substantially frusto-conical shape of a shroud of a flexible endotracheal tube introducer.

FIG. 4A is a schematic illustration of a shroud of a flexible endotracheal tube introducer in a second substantially frusto-conical shape.

FIG. 4B is a schematic illustration showing a longitudinal (sagittal) cross section of a second substantially frusto-conical shape of a shroud of a flexible endotracheal tube introducer.

FIG. 5A shows a shroud of a flexible endotracheal tube introducer in a anteflexed, forward, or distal-ward conformation

FIG. 5B shows a shroud of a flexible endotracheal tube introducer in a retroflexed, rearward, or proximal-ward conformation

FIG. 6 is a schematic illustration of an exemplary endotracheal tube.

FIG. 7A is a schematic illustration showing a flexible endotracheal tube introducer with its

shroud in its anteflexed, forward or distal-ward conformation and having its proximal end placed within a lumen at a distal end of an endotracheal tube.

FIG. 7B is a schematic illustration showing a flexible endotracheal tube introducer advanced into an endotracheal tube so that a ring of the flexible endotracheal tube introducer apposes a beveled distal tip of the endotracheal tube.

FIG. 7C is a schematic illustration showing a shroud of a flexible endotracheal tube introducer flexed from its anteflexed, forward or distal-ward conformation to its retroflexed, rearward or proximal-ward conformation to cover a beveled tip and Murphy eye of an endotracheal tube.

FIG. 7D is a schematic illustration showing a proximal end of a flexible endotracheal tube introducer fixed to a proximal end of an endotracheal tube using a fixation ring, thereby forming a combined endotracheal tube introducer-endotracheal tube unit.

FIG. 7E is a schematic illustration showing a combined endotracheal tube introducer-endotracheal tube unit with a malleable stylet in place in a patient's airway.

FIG. 7F is a schematic illustration showing a shroud of a flexible endotracheal tube introducer in its retro-flexed or proximal-ward position to cover a beveled tip and Murphy eye of an endotracheal tube, about to be withdrawn from an endotracheal tube.

FIG. 7G is a schematic illustration showing a shroud of a flexible endotracheal tube introducer in the process of being its anteflexed to its forward or distal-ward conformation as it is being withdrawn from an endotracheal tube.

FIG. 7H is a schematic illustration showing a shroud of a flexible endotracheal tube introducer in its anteflexed, forward or distal-ward conformation as it is being withdrawn from an endotracheal tube.

FIG. 8A is a schematic illustration of a combined introducer-ETT unit about to be advanced over a fiberscope.

FIG. 8B is a schematic illustration of a combined introducer-ETT unit piggy backed upon a fiberscope.

FIG. 8C is a schematic illustration of a combined introducer-ETT unit piggy backed upon a fiberscope and about to be advanced into a patient's airway.

FIG. 9A is a schematic illustration of an in-place ETT in a patient's airway.

FIG. 9B is a schematic illustration of an in-place ETT in a patient's airway, into which in-place ETT a tube exchanger has been inserted.

FIG. 9C is a schematic illustration of in-place ETT having been withdrawn over a tube exchanger and removed from a patient's airway.

FIG. 9D is a schematic illustration of a combined introducer-ETT unit about to be advanced over a tube exchanger into a patient's airway.

Detailed Description of the Invention

As show in FIG. 1, the present invention comprises a flexible endotracheal tube introducer ("introducer") **100** for slidably removable disposition within an exemplary endotracheal tube ("ETT") **200**, such as, for example, a No. 6.5, No. 7.0, No. 7.5 or No. 8.0 adult ETT.

As shown in FIG. 2, introducer **100** comprises a tubular member **109** having a longitudinal axis **111**, and having a lumen **108**, extending between a split proximal end **101** and a distal end **105** of tubular member **109** and defined by a cylindrical wall **107** that is circumscribed

by a ring **112** to which there is invertibly attached a shroud **110**.

Cylindrical wall **107** of introducer **100** has an inner diameter of about 4.5 millimeters, a thickness of about 1 millimeter and an outer diameter of about 6.5 millimeters. Cylindrical wall **107** of introducer **100** has an outer diameter that is less than an inner diameter of exemplary ETT **200** (shown in FIG. 1).

A first slit **103** in split proximal end **101** of tubular member **109** extends distal-ward for about 1.5 centimeters from a proximal opening **102** of tubular member **109**. A second slit **104** in split proximal end **101** of tubular member **109** is generally parallel to first slit **103** and extends distal-ward for about 1.5 centimeters from proximal opening **102** of tubular member **109**, beginning at a point on cylindrical wall **107** that is about 180 degrees away from first slit **103**.

Ring **112** is adherently fixed to tubular member **109** at a distance of about 4 centimeters from distal end **105** of tubular member **109**. Ring **112** has a radial thickness of about 1 mm and a length of about 1 cm.

FIG. 3A shows that shroud **110** may have a first substantially frusto-conical shape **117** that extends from a first circle **114** in a first plane that is perpendicular to longitudinal axis **111** of tubular member **109** (FIG. 1) and a second circle **115** in a second plane that is parallel to the first plane of first circle **114**. Second circle of shroud **110** is generally coaxial with tubular member **109** (FIG. 1) and is unattached to tubular member **109** (FIG. 1).

FIG. 3b shows a longitudinal cross sectional view taken through first substantially frusto-conical shape **117** of shroud **110**, appearing generally as a parallelepiped having proximal side **119**,

distal side **120**, anterior side **121** and posterior side **122**.

In FIG. 3b, proximal side **119** measures about 6.5 millimeters, distal side **120** measures about 12 millimeters, anterior side **121** measures about 26 millimeters and posterior side **122** measures about 26 millimeters.

FIG. 4A shows that shroud **110** may also have a second substantially frusto-conical shape **118** that extends from first circle **114** in a first plane that is perpendicular to longitudinal axis **111** of tubular member **109** (FIG. 1) to an ellipse **116** in a second plane that is either parallel or other than parallel to the first plane of first circle **114**. Ellipse **116** is unattached to tubular member **109** (FIG. 1).

FIG. 4B shows a longitudinal cross-sectional view taken through second substantially frusto-conical shape **118** of shroud **110**, appearing generally as a parallelepiped having proximal side **123**, distal side **124**, anterior side **125** and posterior side **126**.

In FIG. 4B, proximal side **123** measures about 6.5 millimeters, distal side **124** measures about 13 millimeters, anterior side**125** measures about 26 millimeters and posterior side **126** measures about 33 millimeters.

Ring **112** (FIG. 2) may be manufactured, for example, from silicone, nylon or plastic, as a discrete structure to which shroud **110** is invertibly attached at first circle **114**, or it may be fashioned as an extruded cylinder that is a proximal-ward extension ("neck") of shroud **110** at first circle **114**. Alternatively, ring **112** may be formed as a ring-like radial extrusion of tubular member **109**.

With ring **112** serving as a circumferential pivot about tubular member **109**, shroud **110** may be inverted about ring **112** to assume two conformations: [i] an anteflexed, forward or distal-ward conformation; and, a [ii] a retroflexed, rearward or proximal-ward conformation.

FIG. 5A shows shroud **110** in the anteflexed, forward or distal-ward conformation **110a**. FIG. 5B shows shroud **110** in the retroflexed, rearward or proximal-ward conformation **110b**.

FIG. 6 shows an exemplary ETT **200** in greater detail, comprising an ETT tubular member **209** having an ETT lumen **208** for gas flow, defined by a cylindrical ETT wall **207**, extending between a proximal opening **202** at a proximal ETT end **201** and a distal opening **204** at a distal ETT end **203** of ETT tubular member **209**. Cylindrical wall **207** of ETT **200** has an inner diameter that is greater than the outer diameter of introducer **100** (FIG. 2).

Inflatable cuff or balloon **213** circumscribes ETT tubular member **209** adjacent distal ETT end **203** and communicates with an inflation port **211** via inflation tubing **212**. Proximal end **201** of tubular member **209** is adapted to receive a connector piece **210** into which tubing (not shown in FIG. 6) for gas flow to a patient may be attached.

Distal ETT end **203** of ETT tubular member **209** terminates in a beveled tip whose shorter terminus **205** defines the anterior aspect of ETT **200**. A Murphy eye **206** is fashioned into cylindrical wall **207** of ETT tubular member **209** adjacent distal end **203** to provide an alternative pathways for gas flow to a patient should distal opening **204** of ETT tubular member **209** become occluded.

In an orotracheal intubation, introducer **100** is grasped with shroud **110** in its anteflexed, forward or distal-ward position **110a**, as shown in FIG. 7A. Split proximal end **101** of introducer **100** is placed within ETT lumen **208** at distal end **203** of ETT **200** (FIG. 7A) and advanced into ETT **200** until a proximal end of said invertibly attached shroud, such as ring **112** of introducer **100**, apposes beveled distal tip **205** of ETT **200**, as shown in FIG. 7B. Shroud **110** is then manually flexed from its anteflexed, forward or distal-ward position **110a** to its retroflexed,

rearward or proximal-ward position **110b** to cover beveled tip **205** and Murphy eye **206** of ETT **200**, as shown in FIG. 7C.

Split proximal end **101** of introducer **100** is then fixed to proximal end **201** of ETT **200** by everting the split halves of proximal end **101** of introducer **100** over proximal end **201** of ETT **200**, as shown in FIG. 7D, and using, for example, surgical tape (not shown in FIG. 7D) or a fixation ring **113**, to stabilize the alignment of the respectively shrouded distal ends **105** and **203** of introducer **100** and ETT **200**, now combined as introducer-ETT unit **400**, the proximal aspect of which is shown in FIG. 7D.

Lubrication must be generously applied between shroud **110** of introducer **100** and distal end **203** of ETT **200** to prevent sticking during subsequent withdrawal of introducer **100** from lumen **208** of ETT **200**.

A malleable stylet **300**, shown in FIG. 7E, is inserted into lumen **108** of introducer **100**, now forming combined introducer-ETT unit **400**. Combined introducer-ETT unit **400** is advanced into a patient's airway **500**, as shown in FIG. 7E , to place the shrouded end of combined introducer-ETT unit **400** between and beyond the patient's vocal cords (not shown in FIG. 7E).

Surgical tape or fixation ring **113** is now removed and introducer **100** is withdrawn from ETT **200**. During the withdrawal of introducer **100** from ETT **200**, shroud **110** is anteflexed to forward, distal-ward conformation **110a** by the sliding motion of distal end **203** of ETT **200** relative to wall **107** of introducer **100**, as shown in sequential FIGs. 7F through 7G, when viewed from left to right.

In a nasal intubation, introducer **100** is grasped with shroud **110** in its anteflexed, forward or distal-ward position **110a**, as shown in FIG. 7A. Split proximal end **101** of introducer **100** is placed within ETT lumen **208** at distal end **203** of ETT **200** (FIG. 7A) and advanced into ETT **200** until a proximal end of invertibly attached shroud **110**, such as ring **112** of introducer **100**, apposes beveled distal tip **205** of ETT **200**, as shown in FIG. 7B. Shroud **110** is then manually flexed from its anteflexed, forward or distal-ward position **110a** to its retroflexed, rearward or proximal-ward position **110b** to cover beveled tip **205** and Murphy eye **206** of ETT **200**, as shown in FIG. 7C.

Split proximal end **101** of introducer **100** is then fixed to proximal end **201** of ETT **200** by everting the split halves of proximal end **101** of introducer **100** over proximal end **201** of ETT **200**, as shown in FIG. 7D, and using, for example, surgical tape (not shown in FIG. 7D) or a fixation ring **113**, to stabilize the alignment of the respectively shrouded distal ends **105** and **203** of introducer **100** and ETT **200**, now combined as introducer-ETT unit **400**, the proximal aspect of which is shown in FIG. 7D.

Lubrication must be generously applied between shroud **110** of introducer **100** and distal end **203** of ETT **200** to prevent sticking during subsequent withdrawal of introducer **100** from lumen **208** of ETT **200**.

Combined introducer-ETT unit **400** is advanced into a patient's nostril and thence into the patient's nasopharynx until combined introducer-ETT unit **400** is visualized through the patient's mouth in the patient's oropharynx. Thereafter, the shrouded distal end of combined introducer-ETT unit **400** is grasped with a forceps introduced through the patient's mouth and thence

directed so as to place the shrouded distal end of combined introducer-ETT unit **400** between and beyond the patient's vocal cords (not shown in FIG. 7E).

Surgical tape or fixation ring **113** is now removed and introducer **100** is withdrawn from ETT **200**. During the withdrawal of introducer **100** from ETT **200**, shroud **110** is anteflexed to forward, distal-ward conformation **110a** by the sliding motion of distal end **203** of ETT **200** relative to wall **107** of introducer **100**, as shown in sequential FIGs. 7F through 7G, when viewed from left to right.

In an intubation using a fiberscope, introducer **100** is grasped with shroud **110** in its anteflexed, forward or distal-ward position **110a**, as shown in FIG. 7A. Split proximal end **101** of introducer **100** is placed within ETT lumen **208** at distal end **203** of ETT **200** (FIG. 7A) and advanced into ETT **200** until a proximal end of invertibly attached shroud **110**, such as ring **112** of introducer **100**, apposes beveled distal tip **205** of ETT **200**, as shown in FIG. 7B. Shroud **110** is then manually flexed from its anteflexed, forward or distal-ward position **110a** to its retroflexed, rearward or proximal-ward position **110b** to cover beveled tip **205** and Murphy eye **206** of ETT **200**, as shown in FIG. 7C.

Split proximal end **101** of introducer **100** is then fixed to proximal end **201** of ETT **200** by everting the split halves of proximal end **101** of introducer **100** over proximal end **201** of ETT **200**, as shown in FIG. 7D, and using, for example, surgical tape (not shown in FIG. 7D) or a fixation ring **113**, to stabilize the alignment of the respectively shrouded distal ends **105** and **203** of introducer **100** and ETT **200**, now combined as introducer-ETT unit **400**, the proximal aspect of which is shown in FIG. 7D.

Lubrication must be generously applied between shroud **110** of introducer **100** and distal

end **203** of ETT **200** to prevent sticking during subsequent withdrawal of introducer **100** from lumen **208** of ETT **200**.

As shown in FIG. 8A, a fiberscope **600** is then inserted within lumen **108** of introducer **100**, now forming combined introducer-ETT unit **400**. With introducer-ETT unit **400** effectively "piggy-backed" upon fiberscope **600**, as shown in FIG. 8B, fiberscope **600** is introduced into a patient's airway and is used to identify the patient's carina. Having identified the patient's carina, combined introducer-ETT unit **400** is advanced over fiberscope **600**, using fiberscope **600** as a guide wire, (FIG. 8C) so as to place the shrouded distal end of combined introducer-ETT unit **400** between and beyond the patient's vocal cords (not shown in FIG. 8C).

Surgical tape or fixation ring **113** is now removed and introducer **100** is withdrawn from ETT **200**. During the withdrawal of introducer **100** from ETT **200**, shroud **110** is anteflexed to forward, distal-ward conformation **110a** by the sliding motion of distal end **203** of ETT **200** relative to wall **107** of introducer **100**, as shown in sequential FIGs. 7F through 7G, when viewed from left to right.

In an endotracheal tube exchange, introducer **100** is grasped with shroud **110** in its anteflexed, forward or distal-ward position **110a**, as shown in FIG. 7A. Split proximal end **101** of introducer **100** is placed within ETT lumen **208** at distal end **203** of ETT **200** (FIG. 7A) and advanced into ETT **200** until a proximal end of invertibly attached shroud **110**, such as ring **112** of introducer **100**, apposes beveled distal tip **205** of ETT **200**, as shown in FIG. 7B. Shroud **110** is then manually flexed from its anteflexed, forward or distal-ward position **110a** to its retroflexed, rearward or proximal-ward position **110b** to cover beveled tip **205** and Murphy eye **206** of ETT **200**, as shown in FIG. 7C.

Split proximal end **101** of introducer **100** is then fixed to proximal end **201** of ETT **200** by everting the split halves of proximal end **101** of introducer **100** over proximal end **201** of ETT **200**, as shown in FIG. 7D, and using, for example, surgical tape (not shown in FIG. 7D) or a fixation ring **113**, to stabilize the alignment of the respectively shrouded distal ends **105** and **203** of introducer **100** and ETT **200**, now combined as introducer-ETT unit **400**, the proximal aspect of which is shown in FIG. 7D.

Lubrication must be generously applied between shroud **110** of introducer **100** and distal end **203** of ETT **200** to prevent sticking during subsequent withdrawal of introducer **100** from lumen **208** of ETT **200**.

By analogy with the use of fiberscope **600**, a tube exchanger **700** is now inserted into an in-place ETT **200x** within a patient's airway **500** to serve as a guide wire for removal of in-place ETT **200x** (FIG. 9A and FIG. 9B). In-place ETT **200x** is withdrawn over tube exchanger **700** (FIG. 9C) and thereafter combined introducer-ETT unit **400** is advanced over tube exchanger **700**, using tube exchanger **700** as a guide wire (FIG. 9D), so as to place the shrouded distal end of combined introducer-ETT unit **400** between and beyond the patient's vocal cords (not shown in FIGs. 9A - 9D).

Surgical tape or fixation ring **113** is now removed and introducer **100** is withdrawn from ETT **200**. During the withdrawal of introducer **100** from ETT **200**, shroud **110** is anteflexed to forward, distal-ward conformation **110a** by the sliding motion of distal end **203** of ETT **200** relative to wall **107** of introducer **100**, as shown in sequential FIGs. 7F through 7G, when viewed from left to right, leaving said ETT 200 properly positioned in the patient's trachea.